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SECTION 3 - 510(k) SUMMARY

510(k) Number: K102925

Submitted by: NexGen Medical Systems, Inc.
10471 Double R Blvd, Suite A
Reno, NV 89521 US

Contact Person: John Kucharczyk, CEO
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Date Prepared: March 18, 2011

Name of the Device: NexGen Peripheral Expandable Catheter

Proprietary Name: Undetermined at this time

Common Name: Catheter Introducer

Classification: Catheter Introducer (870.1340)

SUMMARY STATEMENT:

Predicate Device: The NexGen Peripheral Expandable Catheter is substantially equivalent to the Applied Medical Expandable Vascular Sheath cleared under 510(k) K070865 and K963886.

Device Description:

The NexGen Peripheral Expandable Catheter is a sterile single use catheter intended to facilitate the placement or removal of vascular catheters and devices including the NexGen Mechanical Retrieval Device (MRD).

The Device features a Pebax/HDPE catheter shaft attached to a braided Nitinol tip that expands as the device is deployed from the lumen of a guide catheter. The Nitinol braid passively expands to the contour shape of the vessel lumen and allows a separate medical device such as a catheter to be retracted into the Nitinol Braid. Both the Nitinol Braid and the other device are then retracted into the Guide Catheter. The retracted Expandable Catheter with the encapsulated device are then removed together via removal of the Guide Catheter.

The Expandable Catheter comes in multiple expanded profiles of 5mm, 7mm, 9mm and 11mm, each having a working length of 43cm and 116cm. The Expandable Catheter is packaged in a Tear Away Sheath (B. Braun 510(k) K000313) that is used to facilitate loading the catheter into a Guide Catheter.

Proximally located on the catheter shaft is a female luer connection for the attachment to a Hemostasis Valve Y Connector, which provides a means of introducing contrast media or other fluids. The Hemostasis Valve Y Connector is separate or a prepackaged component.

Intended Use: The NexGen Peripheral Expandable Catheter is indicated for percutaneous access to the peripheral vascular system and is designed to assist in the placement and removal of devices. This device is not intended for use in the coronary or cerebral vasculature.

Non-Clinical Testing: The following bench top testing was conducted to verify the device met design specifications:

- Visual / Dimension Inspection
- Catheter Pushability / Trackability Testing
- Catheter Tensile Testing
- Catheter Torque Testing
- Catheter Burst Testing Catheter Leak Testing
- Catheter Kink Diameter Testing
- Catheter Flow Rate Testing
- Catheter Radial Force Testing
- Catheter Corrosion Resistance Testing

Technological Characteristics: The NexGen Peripheral Expandable Catheter is a sterile single use catheter intended for percutaneous access to the peripheral vascular system. The Expandable Catheter is designed to assist in the placement and removal of vascular catheters and devices. The device consists of 2 major components, a catheter shaft and a deployable braided nitinol funnel. The NexGen Expandable Catheter is designed for percutaneous insertion via a standard 8F Guide Catheter. The braided funnel passively expands to the contour shape of the vessel lumen and allows a separated medical device such as a catheter to be inserted and retracted. Both the braided funnel and the other device are then retracted into the Guide Catheter. The retracted Expandable Catheter with the encapsulated device is then removed together via removal of the Guide Catheter. The Expandable Catheter comes in multiple expanded profiles of 5mm, 7mm, 9mm and 11mm, each having a working length of 43cm and 116cm.

The NexGen Expandable Catheter is substantially equivalent to the Applied Medical Expandable Vascular Sheath (K963886 and K070865).

Mechanical, safety and biocompatibility tests were performed to verify the functional safety, structural integrity and material safety. All testing demonstrated that the NexGen Expandable Catheter is comparable to the predicate devices and introduces no new safety and effectiveness issues when used as indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 10 2011

NexGen Medical Systems, Inc.
c/o Craig Pagan
Regulatory Affairs
1050 W NASA Blvd, Suite 136
Melbourne, FL 32901

Re: K102925
Trade/Device Name: NexGen Peripheral Expandable Catheter
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: October 25, 2011
Received: October 26, 2011

Dear Mr. Pagan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 - INDICATIONS FOR USE STATEMENT

510(k) Number: K102925

Device Name: **NexGen Peripheral Expandable Catheter**

INDICATIONS:

The NexGen Peripheral Expandable Catheter is indicated for percutaneous access to the peripheral vascular system and is designed to assist in the placement and removal of devices. This device is not intended for use in the coronary or cerebral vasculature.

CONTRAINDICATIONS:

No known contraindications.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102925